Procter&Gamble

The Procter & Gamble Company
Health Care Research Center
8700 Mason-Montgomery Road, Mason, Ohio, 45040

June 13, 2005

Rec'd VL
JUN 15 2005

via overnight mail

ATTN: Vicki Lutwak

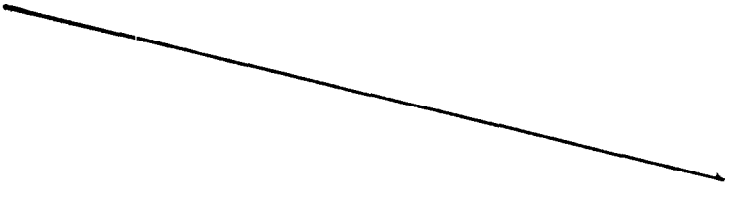
Office of Nutritional Products
Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park , MD 20740-3835

Re: Additional information for NDI Notification; *Bifidobacterium infantis* 35624

Dear Ms. Lutwak,
This letter is to follow up on the June 9th, 2005 conference call between FDA-CFSAN and P&G. We herein submit to FDA additional information to support the 75-day pre-market notification for marketing *Bifidobacterium infantis* Strain 35624 (trade name "*Bifantis*") as a new dietary ingredient. Enclosed with this original letter are two identical copies.

Accession number

As reported to you in our conference call, the correct NCIMB number is 41003.



Antibiotic resistence

In addition to those antibiotics that were addressed on Page 2 of the original NDI submission, we understand you request data on other clinically significant antibiotics such as tetracycline, erythromycin and penicillin. The following table addresses this data requirement.

Antibiotic resistence properties of *Bifidobacterium infantis* 35624

Antibiotic ug/ml	*B. infantis 35624* Susceptibility
Ampicillin 25	
Amoxacillin/Clavulanic Acid 30	
Amikacin 30	
Netilmicin 10	
Trimethoprim 1.25	
Sulfa/Trimethoprim 25	
Teicoplanin 30	
Sodium Cefuroxime 30	
Sodium Ceftaxime 30	
Ceftriaxone 30	
Ciprofloxacin 5	
Gentamicin 10	
Metronidazole 5	
Cephradine 30	
Rifampicin 5	
Vancomycin 5	
Chloramphenicol 10	
Tetracycline 30	
Erythromycin 15	
Nalidixic acid 30	
Chloramphenicol 30	
Novobiocin 30	
Clindamycin 2	
Tricarcillin 75	
Penicillin 10	

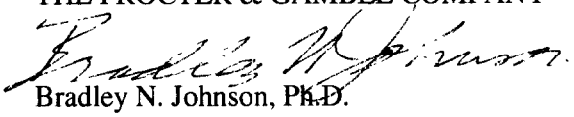
Notes

Assays were conducted using the standard disk diffusion zone of inhibition test protocol. *Bifidobacterium infantis* 35624 was grown in Reinforced Clostridial broth under anaerobic conditions at 37° C for 48 hours. A sterile swab was inserted into this stationary-phase culture and swabbed onto the surface of Reinforced Clostridial Agar plates. Commercially available disks containing the antibiotics were added to the Reinforced Clostridial Agar and zones of inhibition were measured using a micrometer after 48 hours of growth under anaerobic conditions. Classifications of Sensitive, Resistant and Intermediate were assigned based on manufacturers guidelines as well as the Manual of Clinical Microbiology 6th edition for gram positive bacteria.

We hope this letter is fully responsive to FDA's information needs. Should you have any questions regarding this notification, feel free to call me at 513-622-1599, or e-mail to johnson.bn@pg.com. We will respond promptly to any questions you might have.

Sincerely,

THE PROCTER & GAMBLE COMPANY



Bradley N. Johnson, Ph.D.

US Regulatory Affairs, Personal Health Care